II. Amendments to the Specification Pursuant to 37 C.F.R. § 1.121 (b)

Please amend the specification by adding replacement paragraphs [0008], [0010], [0012], [0050] and [0067] as indicated below. Instructions are made by reference to US Patent Application Publication No. 2004/0157766 ("the '766 Appln Pub").

At Page 1 of the '766 Appln Pub, replace the first full paragraph in the second column numbered [0008] with the following paragraph:

> [0008] Benzamycin® (generic name: benzoyl peroxide and erythromycin topical; Dermik Lab.) is a topical gel for the treatment of acne comprising a combination of 3% erythromycin, as a topical antibiotic, and 5% benzoyl peroxide, as an antibacterial, keratolytic and desquamating agent. This combination, however, is unstable at room temperature for the above reason, so that Benzamycin® rapidly loses its pharmaceutical effectiveness if stored at ambient temperature.

At Page 1 of the '766 Appln Pub, replace the third full paragraph in the second column numbered [0010] with the following paragraph:

> [0010] Various attempts have been made to overcome the instability of formulations such as Benzamycin®. U.S. Pat. No. 5,446,028, U.S. Pat. No. 5,767,098 and U.S. Pat. No. 6,013,637, for instance, disclose formulations further comprising a stabilising agent such as dioctyl sodium sulfosuccinate. U.S. Pat. No. 5,466,446 discloses a method for preparing a reportedly stable

formulation comprising clindamycin and benzoyl peroxide by controlling the ratio of each active ingredient. The proprietor of this patent markets a product under the name Clindoxyl® Gel (generic name: clindamycin phosphate and benzoyl peroxide) which contains benzoyl peroxide and clindamycin in the ratio of 5:1 and which has a shelf-life of 60 days at room temperature. The product is, however, required to be kept refrigerated prior to being dispensed, which is inconvenient as well as impractical.

At the bottom of the second column of Page 1 of the '766 Appln Pub continuing to the top of the top of the first column on Page 2, replace the paragraph numbered [0012] with the following paragraph:

[0012] Benzaclin® (generic Name: benzoyl peroxide and clindamycin topical) is the only FDA-approved combination of 1% clindamycin phosphate and 5% benzoyl peroxide gel. Although this can be stored at room temperature (up to 25°C), this is only stable for about two months.

At the bottom of the second column of Page 4 of the '766 Appln Pub continuing to the top of the top of the first column on Page 5, replace the paragraph numbered [0050] with the following paragraph:

[0050] Polymeric delivery systems useful in products of the invention will generally comprise a polymer or polymers in the form of particles (e.g. microparticles), aggregates of particles (e.g. aggregates of microparticles) or clusters of aggregates (agglomerates) of particles (e.g. agglomerates of

microparticles) which are capable of entrapping any desired active for delayed release. The polymer particles will generally be porous (i.e. these have an open structure) and will also typically be cross-linked, e.g. comprising a porous polymeric matrix. Examples of polymeric delivery systems suitable for use in the invention include the Poly-Trap® (INCI Name: Lauryl Methacrylate/ Dimethacrylate Crosspolymer commercially-available from Amcol Health and Beauty Solutions, Inc.) and Poly-Pore® (Allyl Methacrylate Crosspolymer) systems, both commercially-available from Amcol Health and Beauty Solutions, Inc., and, in particular, the Microsponge® system, each as described below.

At Page 6 of the '766 Appln Pub, replace the first full paragraph in the second column numbered [0067] with the following paragraph:

[0067] The carriers may, for example, include conventional formulating ingredients selected from lipophilic base materials (for example fatty (e.g. C_{10-30}) alcohol esters of saturated or unsaturated fatty (e.g. C_{10-30}) acids, such as cetyl ricinoleate; fatty acid esters of sterols such as cholesterol or lanosterol; emollient silicon oils, e.g. polysiloxanes such as dimethicone or cyclomethicone; or terpenes such as .alpha.-bisabolol), hydrophilic base materials (for example polyethylene glycols, hereinafter referred to as PEGs), stabilisers and/or surfactants (for example fatty acids such as palmitic or stearic acid; fatty alcohols such as cetyl or stearyl alcohol; amphiphilic fatty esters, e.g. fatty alcohol esters of mineral acids such as sodium lauryl sulphate, fatty acid esters of polyols such as glyceryl dilaurate or caprylic/capric triglyceride; PEGylated fatty alcohols, e.g. PEG lauryl ethers such as laureth-4; PEGylated sorbitan esters with fatty acids

such as oleic, lauric, palmitic or stearic acid; PEGylated sterols such as PEG-10 soya sterol; polysaccharides such as xanthan gum; is proprietary products such as emulsifying wax; or thickening polymeric stabilisers, humectants (for example diols or polyols such as propylene glycol or glycerol), viscosity modifiers (for example saccharides such as sorbitol), thickeners (for example colloidal or fumed silica or silicates such as magnesium aluminium silicate), preservatives (for example antimicrobials or antifungals such as methyl paraben, propyl paraben, benzyl alcohol, or phenoxyethanol; or antioxidants such as vitamin E, ascorbyl palmitate or butylated hydroxytoluene), pH regulators (for example buffers, e.g. acid/salt combinations such as citric acid/sodium citrate; or bases such as triethanolamine), or anticoagulants (for example disodium edetate).